EU Endocrine Disruptors

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On July 4, 2017, the European Commission's Standing Committee on Pesticides voted in favor of criteria identifying endocrine disruptors, which are a group of compounds that can disrupt the human hormone-signaling endocrine system. Should these criteria go into effect, numerous plant protection products may potentially be withdrawn from usage in the EU, and as a result, the EU's pesticide maximum residue levels (MRLs) for these compounds could also be revoked. The loss of MRLs in the EU for pesticide compounds commonly used in EU-exporting markets could have a major impact on the international trade of agricultural goods. Exporters should be aware of the potential for changes ahead in the EU's regulatory approach to compounds identified as endocrine disruptors, which could eventually lead to restrictions on the use of pesticide products and their residues on foods in the EU.

The EU's "Cut-off" Mandate and the Endocrine Disruptor Criteria

The EU has been working for years to develop a set of criteria for identifying endocrine disrupting compounds. Under the EU's regulation governing pesticide approvals, Regulation (EC) No. 1107/2009, the European Commission (EC) is mandated to "cut-off" from the EU market any compound which may be carcinogenic, mutagenic, or reprotoxic. This cut-off mandate is a hazard-based approach, which judges simply whether a chemical may be inherently dangerous, whereas most international trade principles take into account a risk assessment, which considers the likelihood of exposure and someone being harmed by it. Regulation 1107/2009 also mandates the hazard-based cut-off of substances that are endocrine disruptors; however, scientific consensus is still developing on criteria for identifying such substances.

In June 2016, the EC published a long-awaited draft of its criteria for defining endocrine disruptors. While these criteria do not provide a definitive list of compounds that will be considered endocrine disruptors, the draft confirmed that the EU is moving forward with the hazard-based approach towards regulation. Importantly, this draft contained provisions which would allow a "derogation for use," or exemption, if a compound can be proven to present negligible exposure to humans or if the compound is indispensable for agriculture. However, this initial draft of the criteria was subject to strongly divisive reactions by EU member states and, after an initial feedback period, the EC issued revised criteria in late 2016 that separated the proposal into two parts: one proposing the endocrine disruptor criteria, and the other proposing the exemption provisions. On July 4, 2017, the European Commission's Standing Committee on Pesticides voted in favor of the endocrine disruptor criteria without also moving forward the proposal containing the exemption provisions for critical uses. It is unclear whether the use exemption will come up in a separate vote at a later date, as the European Commission has not released any additional information or committed to a timeline on this proposal.

The criteria that were passed by the Standing Committee were then submitted to the European Council and Parliament for their required approval before implementation. In a surprise move, on October 4, 2017, the European Parliament rejected the EC's recommendation. Members of the European Parliament criticized the proposal, saying it exempted some substances, thus preventing them from being identified as endocrine disruptors in the first place. The European Commission is now considering next steps given this veto.

How the EU Would Apply the Criteria

Should the EU eventually adopt these criteria for identifying endocrine disruptors, it is expected that they will be applied through the EU's existing pesticide reauthorization procedures. This is the process by which the EU regularly reviews compounds which are currently authorized for use on the EU market. Compounds must be reviewed at least once every 15 years. The process is ongoing within the EU's regular multi-year review cycle. This means that any new EU approach towards endocrine disruptors would not be applied to all applicable

compounds on a date certain, but rather over several years as compounds go through their regular review period.

In the past, the EU has been criticized for not being transparent regarding which compounds are entering review. However, beginning in June 2016, the European Food Safety Authority (EFSA) for the first time shared with WTO members a complete list of compounds which would be coming up for review, and has pledged to continue to publish review lists quarterly. This is a positive sign, indicating that the EU is interested in having affected parties weigh in earlier in the EU review process of active ingredients.

What's Next?

Now that the European Parliament has rejected the criteria approved by the European Commission's Standing Committee on Pesticides, the EC is evaluating its options. This is expected to take some time. Eventually a new proposal that takes into account the Parliament's perspective is likely. Once that is passed by the Standing Committee, it will again be sent to the European Parliament and European Council for approval. The two bodies then have three months to either actively reject the criteria, or approve (through no action) for the criteria to become officially adopted. Following this, a six-month transition period would apply, after which the application of the criteria to current and future pesticide reviews would be expected to begin. Had the European Parliament allowed the originally proposed criteria to advance, the system could have been implemented as soon as the spring or summer of 2018. Given the rejection, however, it is unlikely anything will be ready for implementation prior to 2019.

The EU is moving forward cautiously as it finalizes and implements its endocrine disruptor criteria. Part of the EU's hesitancy is that they know they are likely to be threatened with litigation no matter which route they take. If they adopt the criteria that allow for the use of exemptions, they are likely to face lawsuits from environmental and consumer activist groups in the EU. If they adopt the criteria without allowing use exemptions,

they are likely to be subject to international dispute proceedings through the World Trade Organization (WTO) due to the lack of risk assessments.

The major question for exporters is whether the EU will maintain a system of MRL import tolerances, even if a compound is withdrawn from use in the EU over its endocrine disrupting potential. The European Commission has not issued an official position, but has implied it is unlikely to maintain import tolerances for such substances, as it would be legally difficult for the EU to tolerate residues for imports while removing substances domestically. European growers have certainly encouraged this position. This is expected to be a topic of discussion at a Standing Committee meeting in the future.

The U.S. government, as well as the governments of other major exporting nations, has been engaged on this issue through international forums. At the WTO Sanitary and Phytosanitary (SPS) Committee meeting in Geneva in late March 2017, the U.S. delegation submitted a position letter opposing the draft criteria, with other countries in support. The U.S. Department of Agriculture's Foreign Agricultural Service (USDA-FAS) has also sought comments from U.S. industry on the proposed criteria when they were published in 2016, and submitted this feedback to their EU counterparts.

Bryant Christie Inc. provides a range of services which can assist exporters with staying ahead of the EU's changing regulations. BCI provides MRL monitoring services which track the EU's proposed MRL amendments at various stages in this complex process. Additionally, through BCI's advocacy services, we work directly with pesticide registrants as compounds undergo review in the EU to ensure MRL needs for imported foods are taken into consideration in these decisions.

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